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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE Egbert Mundt I-2003.002 US 6825 10/809,176 03/24/2004 **EXAMINER** 31848 7590 07/12/2006 CHRISTOPHER P. SEGLER SALVOZA, M FRANCO G 369 RAMONA AVENUE PAPER NUMBER ART UNIT SALT LAKE CITY, UT 84115 1648 DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary 10/809,176 | | I | | |
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| ## Examiner Examiner Art Unit 1648 | | Application No. | Applicant(s) | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence as Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (3 WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 3 (76 R 1 1996). In orevent, however, may a reply be thinnly filed after SIX (8) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the mainmun statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. If NO period for reply within the set or extended period for reply will by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Applicant by this office above, the mainmunication state the mailing date of this communication, even if threely filed, may reduce any service plates from adjustment. Set 37 CFR 1, r64(b). Status 1) □ Responsive to communication(s) filed on 16 September 2004. 2a) □ This action is FINAL. 2b) □ This action is FINAL. 2b) □ This action is FINAL. 2c) □ This action is final. 2b) □ Since this application is in condition for allowance except for formal matters, prosecution as to the closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) □ Claim(s) 1-19 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) □ Claim(s) is/are allowed. 6) □ Claim(s) is/are rejected. 7) □ Claim(s) 5-12 and 16-19 is/are objected to. 8) □ Claim(s) 5-12 and 16-19 is/are subject to restriction and/or election requirement. Application Papers 9) □ The precification is objected to by the Examiner. 10) □ The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. Application Papers 11 □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). 21 □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(| • | 10/809,176 | MUNDT ET AL. | |
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| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | Paper No(s)/Mail Da 5) Notice of Informal P | nte | 2) |

DETAILED ACTION

Claim Objections

Claims 5-12, 16-19 are objected to under 37 CFR 1.75(c) as being in improper form for being multiply dependent (i.e.: "according to claims 1-4," "according to claims 1-5," "claims 7-9," etc. See MPEP § 608.01(n). Accordingly, claims 5-12, 16-19 have not been further treated on the merits.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-4, drawn to a classic IBDV mutant, classified in class 424, subclass
 184.1.
- II. Claims 13-15, drawn to a method for the preparation of a classic IBDV mutant, classified in class 435, subclass 235.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case virus mutants can be produced using a materially different processes such as using a helper virus or through transfection with plasmids.

Because these inventions are distinct for the reasons given above, have acquired a

separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

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Species Election

This application contains claims directed to the following patentably distinct species:

Once an Invention is elected, further election is required:

- One of the amino acids coding at position 222 (serine or threonine) must be elected as identified in claim 3;
- One of the amino acids coding at position 330 (serine or arginine) must be elected as identified in claim 4;
- One of the amino acid sequences must be elected as identified from SEQ ID NO. 1-5

The species are independent or distinct because:

Mutations; amino acid sequences: The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the amino acid substitutions and the different amino acid sequences encoding different proteins create structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions

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within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such amino acid sequence represents an independent and distinct invention due to structural divergence in sequence and functional divergence for encoding different products, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR 1.141 et seq. (MPEP § 803.04).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 5-12, 15, 17-19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116. Amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner

TECHNOLOGY CENTER 1600

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